BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

GnRH Agents

Policy Number: 9.703
Version Number: 2.1
Version Effective Date: 3/1/2022

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☐ MassHealth - MCO ☐ MassHealth – ACO ☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Eligard (leuprolide)**
- **Lupaneta Pack (leuprolide/norethindrone)**
- **Lupron (leuprolide)**
- **Orilissa (elagolix)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Orilissa: contraindicated in pregnancy, known osteoporosis and severe hepatic impairment
Required Medical Information	**Lupron (leuprolide)** Documentation of one of the following diagnosis: 1. Advanced Prostate Carcinoma; 2. Endometriosis; AND

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

a. An inadequate response, intolerance or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs); AND

b. An inadequate response, intolerance, contraindication to hormonal therapy with one of the following: oral contraceptives, progestins or androgens;

3. Uterine leiomyomas (uterine fibroids); AND

    a. Anticipated surgery date (date of surgery required) or clinical rationale why surgical intervention is not appropriate; OR

4. Central Precocious Puberty and member is between the age of 2 and 12 years;

5. Breast, Ovarian, and Endometrial Cancer

Lupaneta (leuprolide/norethindrone), Orilissa (elagolix)
Documentation of all the following:

1. A diagnosis of endometriosis; AND
2. An inadequate response, intolerance or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs); AND
3. An inadequate response, intolerance, contraindication to hormonal therapy with one of the following: oral contraceptives, progestins or androgens

Eligard (leuprolide)
Documentation of the following diagnosis:

1. Advanced Prostate Carcinoma

<u>Gender dysphoria/gender incongruence treatment</u>

Preferred Agents:
Eligard (leuprolide), Lupron (leuprolide)
Documentation of the one of following:

1. Member is less than 18 years of age; AND

    a. A diagnosis of gender dysphoria/gender incongruent; AND

    b. Have experienced puberty to at least Tanner stage 2; AND

    c. Absence of psychiatric comorbidity that interferes with the diagnostic work-up or treatment; AND

    d. Have adequate psychological and social support during treatment; AND

    e. Demonstrate knowledge and understanding of the expected outcomes of GnRH analog treatment;

    OR

2. Member age is 18 years or older; AND

    a. A diagnosis of gender dysphoria/gender incongruent; AND

    b. Capacity to make a well-informed decision and consent to treatment; AND

    c. Medical or mental issues if present are well-controlled; AND

	d. The regimen is a trans-feminine regimen (male to female); AND e. Failure to achieve physiologic hormone levels or an intolerance with use of oral estrogens and spironolactone
Age Restriction	Central Precocious Puberty: age of 2 to 12 years Orilissa: 18 years or older
Prescriber Restriction	Gender dysphoria/gender incongruence: Medication is being prescribed by or in collaboration with an endocrinologist or medical provider with expertise in transgender medical care or pubertal assessment
Coverage Duration	General: 12 months Endometriosis: 6 months Uterine fibroids: 3 months
Other criteria	Reauthorization: 1. Initial criteria are met; AND 2. Continuation of therapy is clinically appropriate; AND 3. The treatment has been effective and well tolerated; AND 4. Additionally, for Gender Dysphoria, a clinical rationale for not transitioning member to oral estrogens for maintenance after surgery.

Applicable Coding:

Code	Medication
J9217	Leuprolide acetate (depot suspension) 7.5 mg
J9218	Leuprolide acetate, per 1 mg
J9219	Leuprolide acetate implant, 65 mg
J1950	Injection, leuprolide acetate (depot suspension), per 3.25 mg

Clinical Background Information and References

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4. Histrelin Acetate. *Drug Facts and Comparisons*. Facts and Comparisons 4.0 [online]. 2007. Available from Wolters Kluwer Health, Inc.
5. Trelstar Depot [package insert]. Corona, CA: Watson Pharma; November 2004
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15. Guss C, Shumer D, Katz-Wise SL. Transgender and Gender Nonconforming Adolescent Care: Psychosocial and Medical Considerations. Curr Opin Pediatr. 2015 Aug; 26(4): 421–426. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4522917/
16. Rosenthal SM. Transgender youth: current concepts. Ann Pediatr Endocrinol Metab. 2016 Dec; 21(4): 185–192. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5290172/pdf/apem-21-185.pdf

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	9.136 GnRH Agents Policy retired, new policy created. Removed Firmagon, Supprelin LA (histrelin), Trelstar (triptorelin), Triptodur (triptorelin), Vantas (histrelin), Zoladex (goserelin) and moved to NF for QHP.	1/1/2021	P&T Committee
2/24/2021	Policy updated to remove generic leuprolide due to very limited use for these indications. Generic leuprolide will now only be present on Policy 9.808	2/24/2021	P&T Committee
11/11/2021	P&T Annual review: No changes	3/2/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.